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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,637	01/29/2002	Arindam Datta	ETH-1635	7724
27777	7590	02/09/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			HO, UYEN T	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/059,637	Applicant(s) DATTA ET AL.	
	Examiner (Jackie) Tan-Uyen T. Ho	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/28/05; 10/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 9/28/05 and 10/11/05 are acknowledged and considered.
2. After a careful reconsideration of the this application, the indicated allowability of claims 54 and 55 is withdrawn in view of the Wang et al. and Jamiolkowski et al. references.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO98/56312) in view of Jamiolkowski et al. (4,889,119). Wang et al. teach a stent formed of a material comprising an inner layer covered by an outer layer, both layers being of a biodegradable polymeric composition and exhibiting different time periods of degradation, wherein the degradation rate of the inner layer can be slower or faster than the degradation rate of the outer layer base on the thickness and the material composition (see claim 5 of Wang et al. reference). Wherein the inner core being made from poly(lactide), poly(glycolide), polycaprolactone and outer layer may be

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selected from materials such as polycaprolactone, Poly(ortho esters), polyanhydrides, PGA/PLA, PEO/PLA (page 6-7). Wang et al. disclose any of the materials used for the inner layer may be used for the outer layer with appropriate arrangement made for degradation, such as thickness, for example (page 5, lines 11-12). Wang et al. also disclose the outer layer including drug coating material as claimed (see pages 8 and 10). However, Wang et al. do not teach the polymer composition of the inner core comprising a blend composition as claimed. Jamiolkowski et al. disclose a biodegradable polymer comprising a blended composition as claimed for use to make surgical devices so that the surgical devices retain a substantial proportion of their initial strength during critical wound healing period (col. 3, lines 35-42) and rapid soften so that they become impalpable after used.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the material of the outer layer of Wang et al.'s stent with the material as disclosed by Jamiolkowski et al.. Doing so would amount to mere substitution of one material for another within the same art that perform equally well in Wang et al.'s stent. Furthermore, it would have been obvious too one having ordinary skill in the art at the time the invention was made to make the inner core of Wang et al.'s stent with the material as claimed in order to provide the inner core with a great initial strength to support a body lumen wall during critical treatment period and rapid soften so that they become impalpable after used.

Response to Arguments

5. Applicant's arguments filed 7/5/05 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, with the level of ordinary skill at the time the claimed invention was made to use the claimed/known material for making whole or part of a surgical device/stent so that the surgical device/stent may retain a substantial proportion of their initial strength during critical wound healing period and rapidly soften so that they become impalpable after used.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jamiolkowski et al. teach that using the claimed/known materials would provide a better initial strength

for a medical device. The teaching of Jamiolkowski et al. would motivate one ordinary skill in the art to use the claimed/known material for making whole or part of a surgical device/stent so that the surgical device/stent may retain a substantial proportion of their initial strength during critical wound healing period and rapidly soften so that they become impalpable after used.

6. In response to applicant's argument that Jamiolkowski et al. discloses a surgical staples while Wang et al. reference discloses a stent. The examiner's position is that although, stent and staples are two different devices they both need initial strength for either getting through body tissue or to support wall of a body lumen. Therefore, one ordinary skill in the art would use the materials that provide initial strength for surgical devices such as stent or staples or other surgical device that require a great initial strength and rapidly soften and impalpable after used.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731

February 2, 2006